Draft Guidance for Industry and Food and Drug Administration Staff

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Medical Device Reporting for Manufacturers

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: July 9, 2013

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact the MDR Policy Branch, 301-796-6670, MDRPolicy@fda.hhs.gov.

When final, this document will supersede "Medical Device Reporting for Manufacturers" dated March 1997.

US Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Surveillance and Biometrics
Division of Postmarket Surveillance
MDR Policy Branch

Preface

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Draft Guidance for Industry and Food and Drug Administration Staff

Medical Device Reporting For Manufacturers

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. INTRODUCTION

1.1 What is the purpose of this draft guidance document?

This draft guidance document describes and explains the Food and Drug Administration's (FDA, we, us) current regulation that addresses reporting and recordkeeping requirements applicable to manufacturers of medical devices for certain device-related adverse events.[1] These requirements are contained in our Medical Device Reporting (MDR) regulation at Title 21, Code of Federal Regulations (CFR), part 803, as authorized by section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). References to FDA regulations and Federal Register documents, as well as cross-references within this guidance document, are hyperlinked for your convenience.

[1] FDA published a proposed rule entitled "Medical Device Reporting: Electronic Submission Requirements" (74 Fed. Reg. 42203, August 21, 2009, http://edocket.access.gpo.gov/2009/E9-19683.htm). FDA plans to modify this guidance based on any final rulemaking to ensure, as needed, that the recommendations in this guidance are consistent with the final rule.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in guidance documents means that something is suggested or recommended, but not required.

1.2 What is the purpose of the MDR regulation?

The MDR regulation provides a mechanism that allows us (the FDA), as well as you (the device manufacturer), to identify and monitor adverse events (deaths, serious injuries and malfunctions) involving your medical devices. The goal is to detect and correct problems in a timely manner. The requirements of the MDR regulation are enforced under the authority of the FD&C Act. The enforcement mechanisms include seizure, injunction, civil money penalties, and criminal prosecution.

The MDR regulation also includes adverse event reporting and recordkeeping requirements for medical device user facilities (e.g., hospitals, nursing homes) and importers of medical devices, as well as recordkeeping requirements for medical device distributors.

1.3 What are the basic requirements of the MDR regulation that apply to me?[2]

Manufacturers, including foreign manufacturers, of medical devices cleared for marketing in the United States are required to:

- Submit to us reports of MDR reportable events involving their medical devices [21 CFR 803.10(c) and 803.50];

- Develop, maintain, and implement written procedures for the identification and evaluation of all adverse medical device events to determine whether the event is an MDR reportable event [21 CFR 803.17] (for related information, see sections 2.10 and 3.1 of this guidance); and

- Establish and maintain complete files for all complaints concerning adverse medical device events [21 CFR 803.18] (for related information, see section 3.2 of this guidance).

[2] The MDR regulation published on December 11, 1995 (60 FR 63578) also included requirements for manufacturers to submit Annual Certification using FDA Form 3381 and Baseline Reports using FDA Form 3417. The Annual Certification requirement was revoked by the Food and Drug Administration Modernization Act of 1997 and removed from the regulation as published on January 26, 2000 (65 FR 4112). The Baseline Reporting requirement was removed from the regulation effective October 27, 2008 (73 FR 33692 and 73 FR 53686).

1.4 What are "MDR reportable events"?

For manufacturers, "MDR reportable events" are events that manufacturers become aware of that reasonably suggest that one of their marketed devices may have caused or contributed to a death or serious injury, or has malfunctioned and the malfunction of the device or a similar device that they market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur [see 21 CFR 803.3] (see Chapter 2 of this guidance document for a description of "serious injury" and "malfunction" and information for determining when a device malfunction must be reported to us as an "MDR reportable event").

1.5 Is this guidance also intended for user facilities, importers and distributors?

No, this guidance document is intended for only medical device manufacturers. Certain requirements applicable to user facilities, importers, and distributors are summarized in Appendix A to facilitate better understanding of the requirements applicable to manufacturers because manufacturers may receive information about MDR reportable events from these entities. Note that this guidance does address manufacturing activities of user facilities, importers, and distributors that also manufacture devices.

1.6 Where can I obtain help if I have questions about this guidance document or the MDR regulation?

If you have any questions or concerns regarding this guidance document or the MDR regulation, contact:

MDR Policy Branch
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2. MANUFACTURER REPORTING REQUIREMENTS

2.1 What are the reporting requirements that apply to me as a medical device manufacturer?

As a manufacturer of medical devices, you are required to submit reports to us of a reportable death, serious injury, or device malfunction [21 CFR 803.10(c)]. A reportable death, serious injury, or malfunction is based on information a manufacturer receives or otherwise becomes aware of, from any source, which reasonably suggests that one of its marketed devices:

- May have caused or contributed to a death or serious injury [21 CFR 803.3 and 803.50] (see also sections 2.5 and 2.13 of this guidance); or

- Malfunctioned and the malfunction of the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur [21 CFR 803.3 and 803.50] (see also section 2.14 of this guidance).

MDR reportable events generally must be submitted to us within 30 calendar days after the day you become aware of the event [21 CFR 803.10 and 803.50] and are referred to in this guidance document as "30-day reports" or "initial reports." Under some circumstances, a medical device report is required to be submitted within 5 work days after the day you become aware of the need to submit such a report [21 CFR 803.10(c)(2) and 803.53].[3] Reports required to be submitted within 5 work days are referred to in this guidance document as "5-day reports" or "five-day reports." A "work day" is Monday through Friday, except Federal holidays [21 CFR 803.3]. All types of required reports are explained further in this guidance document (see sections 2.18, 2.19, and 2.20 of this guidance).

As stated in a notice published in the Federal Register, 76 FR 12743, Title II, section 227 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85), amended section 519(a) of the FD&C Act, 21 U.S.C. 360i(a), relating to certain malfunction reporting requirements. The notice explains that FDAAA changed malfunction requirements for all class I devices and those class II devices that are not permanently implantable, life supporting or life sustaining, but that pending further FDA notice, these devices currently remain subject to 21 CFR part 803 in order to protect the

[3] You must submit a 5-day report to us no later than 5 work days after the day that you become aware that: (a) an MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health; or (b) we have made a written request for the submission of a 5-day report [21 CFR 803.53].

public health. Consequently, malfunction reports for such devices are currently required to be reported under 21 CFR part 803, as was required pre-FDAAA.

The notice also states that FDA intends to publish in the Federal Register a list of the types of devices that continue to be subject to 30-day reporting under 21 CFR part 803 in order to protect the public health under section 519(a)(1)(B)(i)(III) of the FD&C Act, 21 U.S.C. 360i(a)(1)(B)(i)(III). In addition, FDA intends to, by rulemaking, establish malfunction reporting criteria for devices subject to section 519(a)(1)(B)(ii) of the FD&C Act, 21 U.S.C. 360i(a)(1)(B)(ii). In the interim, all device manufacturers and importers must continue to report malfunctions in full compliance with 21 CFR part 803. FDA plans to modify this guidance based on any future notice to modify the types of devices subject to malfunction reporting under section 519(a)(1)(B)(i)(III) of the FD&C Act, 21 U.S.C. 360i(a)(1)(B)(i)(III), and any final rulemaking to establish criteria for malfunction reporting under section 519(a)(1)(B)(ii) of the FD&C Act, 21 U.S.C. 360i(a)(1)(B)(ii), to ensure, as needed, that the recommendations in this guidance are consistent with the final rule.

2.2 Who is considered to be a manufacturer subject to the reporting requirements of the MDR regulation?

A **"**manufacturer" is any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure [21 CFR 803.3]. The term includes any person who:

- Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;

- Initiates specifications for devices manufactured by a second party for subsequent distribution by the person initiating the specifications; or

- Manufactures components or accessories that are medical devices and that are (1) ready to be used and are intended to be commercially distributed and intended to be used as is, or (2) processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

All manufacturers of medical devices approved or cleared for marketing in the US, including foreign manufacturers who export devices to the US, are subject to the MDR regulation and must submit required reports. US manufacturers of medical devices that are not cleared or approved in the US, but are exported to foreign locations, are also subject to the MDR regulation. Failure to submit required reports is a prohibited act [section 301(q) of the FD&C Act, 21 U.S.C. 331(q)] (however, see section 4.10.1 of this guidance for the circumstances under which FDA generally does not intend to enforce MDR reporting requirements for those devices exported under sections 801(e) or 802 of the FD&C Act).

Any person who reprocesses a single use device for reuse in human beings becomes the manufacturer of the device and is subject to all the requirements applicable to the original manufacturer, including the requirements of the MDR regulation [69 FR 7490].

2.3 When do I "become aware" that an MDR reportable event has occurred?

As a manufacturer, you are considered to have "become aware" of an event whenever [21 CFR 803.3]:

- Any of your employees becomes aware of information that reasonably suggests that an event is required to be reported in a 30-day report or in a 5-day report that we have requested from you; or

- Any of your employees with management or supervisory responsibilities over persons with regulatory, scientific or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware from any information (including any trend analysis) that an MDR reportable event(s) necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. In this case, you must submit a report no later than 5 work days after the day that you become aware.

Please note: The Quality System (QS) regulation requires you to have a formally designated unit to receive, review and evaluate complaints [21 CFR 820.198(a)]. Manufacturers who are subject to the QS regulation should ask all of their employees to immediately forward device-related complaints to that unit (see also sections 2.10, 2.11, 2.12 and 3.1 of this guidance).

2.4 What is "information that reasonably suggests" that an MDR reportable event has occurred?

This means any information, including professional, scientific, or medical facts, observations, or opinions that would cause you to come to a reasonable conclusion that a device has caused or may have caused or contributed to an MDR reportable event [21 CFR 803.20(c)]. We also consider trend analyses to be the type of information that may reasonably suggest an MDR reportable event has occurred. For guidance on when an adverse event does not have to be reported to us, see section 2.16 of this guidance.

2.5 What is meant by "caused or contributed" to a death or serious injury?

This means that a death or serious injury was or may have been attributed to a medical device or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of [21 CFR 803.3]:

1. Failure;
2. Malfunction;
3. Improper or inadequate design;
4. Manufacture;
5. Labeling; or
6. User error.

2.6 What is device "user error" and why do you want to know about events involving user error?

We consider a device "user error" to mean a device-related error or mistake made by the person using the device. The error could be the sole cause of an MDR reportable event, or merely a contributing factor. Such errors often reflect problems with device labeling, the user interface, or other aspects of device design. Thus, FDA believes these events should be reported in the same way other adverse events a device causes or contributes to should be reported. This is especially important for devices used in non-health care facility settings.

2.7 What form must I use to submit an MDR reportable event?

Your submission must use FDA Form 3500A (MedWatch) or an electronic equivalent approved by FDA [21 CFR 803.11 and 803.14]. We recommend you consider the content (based on the information required for mandatory adverse event reports) and FDA's ability to process, review, and archive when considering the use of an electronic equivalent report form. We have identified mandatory adverse event reports as a type of document that may be submitted electronically[4] (see also section 2.31 of this guidance for information about the electronic submission of MDR events).

2.8 What information must be included in my report?

Your report must contain all the information required by 21 CFR 803.52 that is known, or reasonably known to you. Information we consider reasonably known to you includes any information [21 CFR 803.50(b)]:

- That you can obtain by contacting a user facility, importer, or other initial reporter;
- That is in your possession; or
- That you can obtain by analysis, testing or other evaluation of the device.

There are instructions for completing Form 3500A and a coding manual for specific items on the form. The form and the instructions for completing the form can be

[4] The CDRH May 8, 2008 notification is posted on the Part 11 Docket at FDA-1992-S-0039-0054.

obtained at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions/default.htm. The coding manual can be obtained at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm106737.htm. Instructions for electronic reporting are available at the electronic Medical Device Reporting (eMDR) - Home Page.

2.9 Can I include multiple devices in the same report?

Although a user facility may submit one report for an adverse event that involves multiple suspect devices, a manufacturer should submit a separate report for each suspect device involved in the MDR reportable event.[5] For example, if you receive a report from a user facility which indicates that more than one of your devices may have been involved in one MDR reportable event, and you cannot determine which device actually caused or contributed to the event or which device malfunctioned, you should submit a separate report for each device potentially involved in the event.

2.10 What do you consider to be a device-related complaint and do I have to evaluate the complaint?

For the purposes of this guidance document, we recommend that you use the definition of a complaint found in the QS regulation, which defines a complaint as:

> [A]ny written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution [21 CFR 820.3(b)].

You are required to review and evaluate all device-related complaints to determine whether the complaint represents an MDR reportable event [21 CFR 803.18(e) and 820.198].

2.11 Where will device-related complaints come from?

You may receive complaint information from many different sources, including telephone calls or other verbal communication, FAX transmissions, written correspondence, sales representative reports, service representative reports, scientific articles (literature), internal analyses, and legal documents. You may receive reports directly from user facilities, importers, or voluntary reporters. We may also send you a communication, such as a copy of a user facility or voluntary report.

FDA believes that manufacturers have a responsibility to inform all employees, including marketing, sales, engineering, manufacturing, regulatory, legal, installation, and service

[5] See Instructions for Completing FDA Form 3500A – General Instructions.

personnel, to immediately forward adverse event information to the appropriate person appointed by those entities to submit MDR reports. Thus, FDA generally considers that a manufacturer becomes aware of an adverse event whenever any employee becomes aware of an adverse event (see section 2.20 of this guidance for the specific employees FDA expects to be able to recognize that an adverse event requiring "remedial action" to prevent a risk of substantial harm to the public has occurred). Employees should be trained to properly identify, collect, and report complaints to your formally designated complaint handling unit [see 21 CFR 820.198(a) for requirements related to complaint files].

User facilities and importers have specific mandatory reporting requirements [see, e.g., 21 CFR 803.10, 803.11, 803.20, 803.30, and 803.40]. If a user facility calls you to report a death or a serious injury, we suggest that you remind the user facility to complete Form 3500A within 10 work days after the day that it becomes aware of a reportable event and send the report to you. If the report involves a death, the user facility must also send the report to us.

It is to your advantage to help user facilities and importers gain an understanding of their reporting obligations. If a user facility or importer uses the MedWatch Form 3500A to report information to you about a reportable event, you can add your manufacturer information to that form. If a user facility or importer does not use a MedWatch Form 3500A to report information to you about an adverse event that is reportable under MDR, you need to provide information for all appropriate sections of the Form 3500A (or electronic equivalent). In some cases, you may need to determine whether the event is MDR reportable by your firm.

You may also receive adverse event information on a voluntary MedWatch Form 3500 when there is no mandatory reporting obligation for the reporting entity (such as user facilities reporting malfunctions or physicians and consumers reporting deaths, serious injuries or malfunctions).

If it is not apparent from the form whether it is an MDR reportable event, then FDA considers the required time period for you to report as beginning when your investigation determines you have information to reasonably suggest that it is an MDR reportable event. Once you determine that the event is MDR reportable, you must submit the report to us within the required time frame [see, e.g., 21 CFR 803.10, 803.11, 803.20, 803.50, and 803.52]. You must submit a completed Form 3500A to us within 30 calendar days or 5 work days, whichever period of time is applicable [see, e.g., 21 CFR 803.10, 803.20, 803.50, and 803.53].

2.12 What are my responsibilities for investigating a voluntary report when the source of the report is unknown to me?

In this case, you must evaluate the complaint to determine whether it represents an MDR reportable event [21 CFR 820.198(a) and 803.18]. Your evaluation must include information in your possession or information you can obtain by contacting a user

facility, importer or other initial reporter related to the adverse event [21 CFR 803.50]. Such information would include what is provided in the voluntary report, along with your knowledge of the device [21 CFR 803.18; see also 21 CFR 803.17, 803.50(b), and 820.198]. Your decision about whether or not the event is an MDR reportable event should be based on the findings of your evaluation.

2.13 What is a "serious injury"?

An injury must meet the definition of "serious injury" in 21 CFR 803.3 for an event to be reportable as a serious injury. A "serious injury" is an injury or illness that [21 CFR 803.3]:[6]

- Is life threatening;
- Results in permanent impairment of a body function or permanent damage to a body structure; or
- Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

"Permanent" means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage [21 CFR 803.3]. Note that not all cosmetic damage will be considered trivial.[7] Furthermore, a life-threatening injury meets the definition of serious injury, regardless of whether the threat was "temporary."[8]

It should also be noted that a device does not have to malfunction for it to cause or contribute to a serious injury. Even though a device may function properly, it can still cause or contribute to a death or serious injury (see section 2.5 of this guidance for further discussion about caused or contributed).

2.14 What is a malfunction and when must a malfunction be reported?

"Malfunction" means the failure of a device to meet its performance specifications or otherwise perform as intended [21 CFR 803.3]. Performance specifications include all claims made in the labeling for the device.

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[6] One court agreed that "[a]lthough some of these consequences may be deemed clinically insignificant, they are considered to be serious injuries when coupled with the interventions, e.g. administration of antibiotics or other medications, explant, reconstruction, debridement, or revision surgery)." TMJ Implants, Inc. v. U.S. Dep't of Health & Hum. Servs., 584 F.3d 1290, 1301 (10th Cir. 2009).

[7] See the FDA response to comment 18 in Medical Devices; Medical User Facility and Manufacturer Reporting, Certification and Registration; Final Rule, 60 Fed. Reg. 63578, 63586 (Dec. 11, 1995).

[8] *See id.* at 63587.

You do not need to assess the likelihood that a malfunction will recur. We presume that once the malfunction has occurred it will recur. In the preamble to the 1995 MDR final rule,[9] we state that a malfunction is reportable if any one of the following is true:

- The chance of a death or serious injury occurring as a result of a recurrence of the malfunction is not remote;

- The consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury;

- The malfunction results in the failure of the device to perform its essential function and compromises the device's therapeutic, monitoring or diagnostic effectiveness, which could cause or contribute to a death or serious injury or other significant adverse device experiences required by regulation. (The essential function of a device refers not only to the device's labeled use, but also to any use widely prescribed within the practice of medicine.);

- The malfunction involves:

  a long-term implant or

  a device that is considered to be life-supporting or life-sustaining and thus is essential to maintaining human life; or

- The manufacturer takes, or would be required to take, an action under section 518 or 519(g)[10] of the FD&C Act as a result of the malfunction of the device or other similar devices (see explanation of "similar device" below, and see section 2.21 of this guidance for an explanation of "remedial action").

Although some may read the fourth criteria above as suggesting that anytime a malfunction of a long-term implant occurs it is per se reportable, that is not our intent. The malfunction of a long-term implant is reportable only when the malfunction would be likely to cause or contribute to a death or serious injury if it were to recur.

Malfunctions that are not likely to cause or contribute to a death or serious injury if they recur do not have to be reported.

We consider a malfunction that is or can be corrected during routine service or device maintenance to be an MDR reportable event if the recurrence of the malfunction is likely to cause or contribute to a death or serious injury. The fact that such a malfunction may be corrected does not change the fact that the device failed to meet its performance specifications or otherwise perform as intended.

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[9] *See id.* at 63585.

[10] The preamble reference is section 519(f), but the appropriate designation for the section is now section 519(g) due to amendments to the FD&C Act.

We generally consider a device to be "similar" to another device if the devices have the same:

- Basic design and performance characteristics related to device safety and effectiveness;
- Intended use and function; and
- Device classification and product code.

Devices that differ only in minor features unrelated to safety or effectiveness can be considered similar devices. Other factors that we recommend to be used to determine whether devices are similar include: brand name, common name, and whether the devices were introduced into commercial distribution under the same 510(k) or the same pre-market approval application (PMA) number.

2.15 How do I decide whether a malfunction is "likely to" cause or contribute to a death or serious injury?

Malfunctions that are reportable are those that reasonably suggest that one of the manufacturer's marketed devices would be "likely to" cause or contribute to a death or serious injury if the malfunctions were to recur, even if the manufacturer may not have received information that the malfunction has caused or contributed to a death or serious injury. We describe certain malfunctions that we consider to be reportable in section 2.14 of this guidance.

For malfunctions other than those described in section 2.14 of this guidance, once the malfunction has caused or contributed to a death or serious injury, it is presumed that the malfunction is also "likely to" cause or contribute to a death or serious injury if it were to recur. Therefore, once a malfunction causes or contributes to a death or serious injury, you have an obligation to file MDRs for additional reports of that malfunction.

You should investigate and conduct follow-up to all additional complaints of such a malfunction to determine whether there have been any further deaths or serious injuries attributable to the same malfunction. A record of the investigation of the complaints must be maintained as part of your MDR files in accordance with the MDR and QS regulations [21 CFR 803.18 and 820.198]. Documentation that a malfunction has not caused or contributed to any additional deaths or serious injuries can be used to support a request for an exemption from further reporting of this malfunction in accordance with the procedures in section 2.27 of this guidance.

2.16 When does a complaint concerning a possible MDR reportable event not have to be reported?

You must investigate all complaints of adverse events [21 CFR 803.17, 803.18, and 820.198]. However, you are not required to submit an MDR report when:

- You have information that would lead a person who is qualified to make a medical judgment to reasonably conclude that your device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers. You must keep in your MDR event files the information the qualified person used to make the reporting decision [21 CFR 803.20(c)(2)].

- You determine that the information that you received is erroneous in that a device-related adverse event did not occur [21 CFR 803.22(b)(1)].

- You determine that you did not manufacture the device [21 CFR 803.22(b)(2)].

- You become aware of information from multiple sources regarding the same patient and the same event [21 CFR 803.22(a)]. One report is required for the event when first reported and information from other sources may require the submission of a supplemental report to the initial MDR report.

You should retain documentation of erroneous complaints and your conclusion that an event is not an MDR reportable event in your MDR files for two years from the date of the event or a period equivalent to the expected life of the device, whichever is greater. The term "expected life" is explained in section 3.2 of this guidance [see 21 CFR 803.18(c), 803.20(c)(2), and 803.22(b)(1)]. In addition, any reportable event information that is erroneously sent to you because it is a device made by another manufacturer must be sent to us with a cover letter explaining that you do not make the device in question [21 CFR 803.22(b)(2)].

2.17 If I am a contract manufacturer, how do I obtain an exemption from reporting?

For devices manufactured under contract, both the firm that actually manufactured the device ("Firm A") and the firm that initiated the specifications and distributed the device ("Firm B") are considered a "manufacturer" based on the definition of that term in 21 CFR 803.3. Under 21 CFR 803.3, both the firm that manufactures the device and the firm that initiates the specifications for the device are manufacturers who are required to report. Under 21 CFR 803.10(c), a manufacturer is required to submit reports. Thus, both Firms A and B are responsible for filing reports on MDR reportable events involving their device.

However, if Firm A and Firm B decide they want only Firm A or Firm B to file the reports for the device, the firm seeking the exemption must submit a request to us for an exemption from filing under 21 CFR 803.19(b). We recommend that the two firms

submit a joint request specifying which firm will submit the reports. Reporting exemptions are described in section 2.26 of this guidance. Instructions for submitting a request for exemption to us are in section 2.27 of this guidance. The request for exemption should provide a description of any agreement between the firms pertaining to MDR reporting for events involving the device. Both firms should maintain documentation of such agreement in their MDR procedures. Such an agreement does not negate a manufacturer's responsibilities to comply with any exemptions, variances, or reporting alternatives that the FDA grants, or any other applicable requirement. Information about the events, including any information about root cause and corrections, should be maintained by both firms. Additional conditions for this type of exemption will be specified in our written response to your request.

We may condition our approval of such an exemption on agreement by the firm requesting the exemption from reporting to be responsible for ensuring that the required reports are, in fact, submitted to FDA. If Firm A is designated to submit the MDR reports, but failed to do so, we would consider such a failure to report to be sufficient grounds to revoke Firm B's exemption from reporting. If revoked, both Firms A and B would be required to report MDR reportable events in compliance with all applicable MDR regulations.

2.18 What types of reports are required by the MDR regulation?

You are required to submit three types of MDR reports. Each type of report must be submitted within the mandatory time frame. The following are the three types of reports:

1. 30-day (initial) reports [21 CFR 803.10(c). 803.20 and 803.50].
2. 5-day reports [21 CFR 803.10(c), 803.20 and 803.53].
3. Supplemental reports [21 CFR 803.10(c) and 803.56].

2.19 What are 30-day reports?

A "30-day report" is the initial MDR report that must be submitted within 30 calendar days after the day you become aware of a reportable device-related death or serious injury, or a reportable malfunction [21 CFR 803.10(c), 803.20 and 803.50]. The report must be submitted as described in section 2.7 of this guidance. You will ordinarily submit 30-day reports for MDR reportable events, but you may be required to submit 5-day reports under certain circumstances as described in section 2.20 of this guidance.

Information that must be provided in your initial report includes:

- Patient information [21 CFR 803.52(a)];
- Information about the adverse event or device problem [21 CFR 803.52(b)];
- Device information [21 CFR 803.52(c)];

- Initial reporter information [21 CFR 803.52(d)];

- Reporting information, including manufacturer contact information, and the report sources, date, type, and number [21 CFR 803.52(e)]; and

- Other information about the device and event [device manufacturer information, 21 CFR 803.52(f)].

2.20 What are 5-day reports?

A "5-day report" (or five-day report) is a report that must be submitted to us within five work days after the day you become aware of an MDR reportable event:

- That necessitates remedial action to prevent an unreasonable risk of substantial harm to public health (remedial action is described in section 2.21 of this guidance); or

- For which we have made a written request for the submission of 5-day reports [21 CFR 803.10(c), 803.20, 803.53].

We consider the 5-day time frame for a report of an event requiring remedial action, as in the first bullet above, to begin the day after an employee with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person whose duties relate to the collection and reporting of adverse events, "becomes aware" of the event [21 CFR 803.3]. We do not expect employees such as non-technical staff to recognize that an adverse event(s) requires remedial action to prevent a risk of substantial harm to the public.[11]

However, when you receive a written request for 5-day reports from us, you must submit the applicable reports within 5 work days after the day any employee becomes aware of the event [21 CFR 803.10(c), 803.20, 803.53].

2.21 What is a "remedial action," and are all adverse events associated with "remedial actions" reportable to FDA as 5-day reports?

Under the MDR regulation, a "remedial action" is any action, other than routine maintenance or servicing of a device, necessary to prevent recurrence of an MDR reportable event [21 CFR 803.3]. FDA does not consider an action taken to correct only a single device involved in an MDR reportable event to be a remedial action.

A decision that a remedial action is necessary can be based on any information, including the occurrence of one or more MDR reportable events, or internal analyses, such as trend analyses, using appropriate statistical or other acceptable methodologies [21 CFR

[11] See 60 Fed. Reg. at 63581-63582.

803.53(a)]. Not all MDR reportable events requiring remedial actions need to be submitted as 5-day reports. Only events that require remedial actions to prevent an unreasonable risk of substantial harm to the public health or events for which FDA requests such a report must be submitted as 5-day reports [21 CFR 803.53]. When the remedial action taken is not required to address an unreasonable risk of substantial harm to the public health [21 CFR 803.50] the reportable adverse events must be submitted as 30-day reports instead of 5-day reports.

If your firm initiates a remedial action in response to an adverse event that FDA would consider a Class I recall because there is "a reasonable probability that the use of, or exposure to" the device "will cause serious adverse health consequences or death," your firm must submit the MDR report for the adverse event within 5 work days of the decision to initiate the remedial action because this is a remedial action to prevent an unreasonable risk of harm to the public health [21 CFR 7.3(m), 803.53].

If your firm has filed an initial MDR report for an event and later decides to take remedial action to address the reported device problem, your firm must file a supplemental MDR report that identifies the remedial action taken in response to the reported problem [21 CFR 803.10(c)(3), 803.56].

Once you have made a determination to initiate a remedial action to prevent an unreasonable risk of substantial harm to the public health, and have filed 5-day report(s) for the event(s) that caused your firm to recognize the need for this remedial action, any subsequent additional reportable events associated with that specific remedial action (i.e., events that do not necessitate a new remedial action) must be filed as 30-day reports.

The Remedial Action Exemption (RAE) Guidance document [RAE Guidance] lists criteria under which FDA will consider granting an exemption from a reporting requirement under 21 CFR 803.19.

You are reminded that a report of correction or removal initiated to reduce a risk to health that the device poses or to remedy a violation of the FD&C Act caused by the device that may present a risk to health, unless already reported to FDA, must be reported to the appropriate FDA district office within 10 working days of initiating such correction or removal, and must contain the information required under 21 CFR 806.10.

2.22 What are supplemental reports and when are these reports required to be made?

A "supplemental" or "follow-up report" is a report you submit whenever you obtain information not known or available to you at the time you submitted your initial 30-day or 5-day report [21 CFR 803.56]. We consider a supplemental report to be required when new facts prompt you to alter or supplement any information or conclusions contained in the original MDR or in any prior supplemental reports.

The supplemental information must be submitted within one month (30 calendar days) following receipt of the information [21 CFR 803.56]. Note: Information on sending supplemental reports electronically is available at eMDR – electronic Medical Device Reporting. Supplemental reports may be sent electronically even if the original report was submitted on paper.

You must include only the new, changed or corrected information in the appropriate portion(s) of the respective form(s) for reports that cross reference previous reports. [21 CFR 803.56(c)]. In your report, you must also [21 CFR 803.56]:

- Indicate in the report being submitted (as well as on the envelope if you are mailing a paper supplemental report) that your submission is a "supplemental" or "follow-up" report; and
- List the appropriate identification number of the report that you are updating with the supplemental information (i.e., the manufacturer report number of the initial MDR).

See 21 CFR 803.52 for additional requirements. You do not need to submit a supplemental report for new information if you would not have been required to report that information had it been known or available at the time you filed your initial MDR.

You must maintain all supplemental reports in your MDR files [21 CFR 803.18]. You must also document in your files when you decide not to submit any new information in a supplemental report [21 CFR 803.18].

2.23 What level of effort must I make to obtain additional information or previously unknown information about MDR reportable events?

The level of effort you make to obtain additional information depends largely on the nature and severity of the event reported. MDR follow-up investigations should involve a "good faith effort" to obtain information and should not focus only on the number of attempts to obtain such information.

A "good faith effort" to obtain additional information should include at least one written request for information. Your MDR files should include a record of each attempt to obtain information, and the nature of the response by the reporter [see 21 CFR 803.50(b)(3) and 803.18(e)]. You should make an effort to obtain correct and complete information about the patient outcome. If you receive a report of a device malfunction, you should determine if a patient was involved and, if so, what happened to the patient as a result of the malfunction. If the patient died or suffered a serious injury, then your initial report must reflect that fact [21 CFR 803.52(b)]. If your initial report was submitted as a malfunction and you learn a patient died or suffered a serious injury, then your supplemental report should change the event type to death or serious injury, as appropriate [21 CFR 803.52(f)(1)].

All of this information is subject to review by us to determine if you made a "good faith" effort to follow-up and obtain the requested information [21 CFR 803.18(b)(2)].

2.24 When will you request additional information from me about an event for which I submitted an MDR report?

We may request that you submit additional information if and when we determine that protection of the public health requires additional or clarifying information [21 CFR 803.15]. In these instances, we will notify you in writing about the additional information required. Any request we make will state the reason or purpose for requesting the information, specify the date by which the information is to be submitted, and clearly relate the request to a reported event. We will confirm all verbal requests for additional information in writing [21 CFR 803.15].

Note that a response to a request for additional information may be made electronically even for reports that were initially filed via hard copy.

2.25 Must reports be made in English?

Yes, all written or electronic MDR reports, including any supplemental reports or requested additional information must be in English [21 CFR 803.13(a)].

2.26 Does the MDR regulation provide for any reporting exemptions, variances, or alternative forms of reporting?

The regulation explicitly exempts the following three types of persons or entities [21 CFR 803.19(a)]:

- Licensed practitioners who prescribe or administer devices intended for use in humans, and who manufacture or import devices solely for use in diagnosing and treating persons with whom the practitioner has a "physician-patient" relationship;

- An individual who manufactures devices intended for use in humans solely for such person's use in research or teaching and not for sale, including any person who is subject to alternative reporting requirements under the Investigational Device Exemption (IDE) regulation (21 CFR part 812), which requires the reporting of all adverse device effects; and

- Dental or optical laboratories.

The regulation also allows you to submit a written request for an exemption, variance or alternative form of reporting for some or all of the requirements of the MDR regulation [21 CFR 803.19(b) and (c)]. We will review your request and will provide a written response to grant or deny, in whole or in part, such request. An exemption, variance, or

alternative form of reporting can also be granted at our discretion in the absence of a request and may impose other reporting requirements to ensure the protection of the public health [21 CFR 803.19(c)]. We can revoke or modify in writing any grant of a written request for an exemption, variance, or alternative form of reporting if we decide that revocation or modification is necessary for the protection of the public health [21 CFR 803.19(d)].

Several variances have been issued with alternatives for providing the manufacturer report number on Form 3500A (see section 2.28 of this guidance). An alternative form of reporting may also allow for a modification in the timing of report submissions and may authorize a reduction in the data elements required by 21 CFR part 803. For example, a firm may request that instead of reporting all of the required information for each event within 30 calendar days after becoming aware of the event, that the reports be submitted quarterly, semiannually or annually and contain only a subset of the data required by the MDR regulation.

You must submit any reports or information required, and abide by any conditions imposed, by our response letter. The conditions imposed in our response will replace or supersede applicable reporting requirements under the MDR regulation until such conditions are revoked or modified [21 CFR 803.19(e)].

2.27 What information should I include in a request for an exemption, variance, or alternative form of reporting and where should the request be sent?

The requirements for exemptions and how to request one are found in 21 CFR 803.19(b). We have issued certain guidances for exemptions, such as the Alternative Summary Reporting (ASR) and Remedial Action Exemption (RAE) guidances (see section 2.28 of this guidance), which contain specific instructions for how you may request certain exemptions. For other exemption requests, you should provide the following information, as applicable:

1. Firm identification, including reporting site registration number and the name, address, and telephone number of the contact person;

2. Type of exemption requested. For example:

    - A total exemption from the MDR requirements, or

    - A request to designate an authorized reporter for manufacturer/importer (see section 2.32 of this guidance) or manufacturer/contract manufacturer (see section 2.17 of this guidance), where both entities are subject to reporting;

3. Type of events involved (e.g., serious injuries, malfunctions);

4. Device identification such as brand name, model, or catalog number and product classification code;

5. Description of the specific type of device problem(s) or adverse event(s) you would like us to consider for the exemption or alternative reporting;

6. Justification for the request, including why you believe FDA does not need to receive the information required by Form 3500A for the affected events; and

7. Number of the affected events reported annually.

Your written request should be on your firm's letterhead with the original signature of the requester. You may call our MDR Policy Branch if you have any questions or need help. Our telephone number is (301) 796-6670.

You can mail your written request to:

MDR Policy Branch
Division of Postmarket Surveillance
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Building 66 - Room 3217
Silver Spring, MD 20993-0002

Alternatively, you can send a PDF version of your signed request letter in an e-mail to:

MDRPolicy@fda.hhs.gov

2.28 Have you published any guidance documents describing the exemptions, variances, and alternative forms of reporting you have issued, and if so, where can I get this information?

Yes, we have published the following guidance documents:

- Medical Device Reporting – Alternative Summary Reporting (ASR) Program.
- Medical Device Reporting - Remedial Action Exemption; Guidance for FDA and Industry [RAE Guidance Document].
- Needle sticks - Medical Device Reporting Guidance for User Facilities, Manufacturers, and Importers [Needle sticks].
- MDR Guidance Document No. 1 - IOL - E1996004 [IOL Exemption].
- Variance from Manufacturer Report Number Format (Variances Nos. 1-4) - [Report Number Variance].
- Variance from Manufacturer Report Number Format – No. 5 [Report Number Variance 5].

- Draft Guidance for Industry, User Facilities and FDA Staff: eMDR - Electronic Medical Device Reporting.
- Draft Guidance for Industry and FDA Staff: Medical Device Reporting for Manufacturers (superseded by this guidance when final).

2.29 Where do I send my MDR reports?

All MDR reports submitted on paper, including reports with a return receipt request, should be sent to [21 CFR 803.12(a)]:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, MD 20847-3002

We generally accept more than one type of report per envelope. If multiple types of reports are enclosed, the envelope should be labeled indicating each type of report enclosed.

To ensure the proper processing of all reports, the outside of the envelope should be labeled according to the following table:

TYPE OF MDR REPORT	IDENTIFICATION OF ENVELOPE (place in lower left-hand corner of the envelope above bar code level)
5-Day (Form 3500A)	5-day Report
30-Day (Form 3500A) or initial	30-day Manufacturer Report
Supplemental (Form 3500A)	Manufacturer Supplemental Report

When we receive your report, we record the postmarked date on the envelope as the date your report was received by us.

For MDRs submitted electronically, see section 2.31 of this guidance.

2.30 Where do I report a public health emergency?

If you believe that there is a public health emergency, you may contact: FDA's Office of Crisis Management, Emergency Operations Center by 24 hour telephone at: 301-796-8240 or toll free at 866-300-4374. You should follow your telephone contact with an e-mail to emergency.operations@fda.hhs.gov or a FAX to 301-847-8543 [21 CFR 803.12(c)].

If you make a report of an emergency by telephone, e-mail, or FAX, and the emergency concerns an MDR reportable event, you are still required to send a written report of the event, using Form 3500A, to the address listed in section 2.29 of this guidance, or in an approved electronic equivalent [21 CFR 803.10, 21 CFR 803.50, and 21 CFR 803.52].

2.31 Where can I find more detailed information on preparing an electronic MDR?

Information on how to prepare an electronic submission is available at CDRH: electronic Medical Device Reporting (eMDR) - Home Page and the FDA Electronic Submissions Gateway.

2.32 I'm a foreign manufacturer. Can the firm that imports my devices to the US file MDR reports that satisfy both the manufacturer and importer reporting requirements? What is the process to request this?

Under the MDR regulation, an importer is required to fill out Blocks A, B, D, E and F on Form 3500A [21 CFR 803.42]. Importers must submit death and serious injury reports to us (with a copy to the manufacturer) and malfunction reports to the manufacturer [21 CFR 803.40].

Manufacturers (including foreign manufacturers) are required to submit MDRs with Blocks G and H, in addition to Blocks A, B, D and E, completed on Form 3500A [21 CFR 803.52]. Manufacturers must submit death, serious injury, and malfunction reports to us [21 CFR 803.50].

If a foreign manufacturer and importer decide they want the importer to file the reports for adverse events involving a product for which they both have an MDR obligation, the foreign manufacturer must submit a request to us for an exemption from filing under 21 CFR 803.19(b). However, we recommend that the importer and foreign manufacturer submit a joint request to us for an exemption from filing, specifying that the importer will submit the reports. The request should also specify whether the importer will submit the malfunction reports as well as the death and serious injury reports to us and whether the importer will submit the reports for reportable adverse events occurring outside the US as well as the US events. We will advise the firms of the special reporting requirements that must be met in the letter that grants the exemption (see section 2.27 of this guidance for instructions to request a reporting exemption). The importer will then be expected to submit a complete Form 3500A that satisfies the obligations of both the importer and manufacturer (completing all parts of the Form 3500A except Block C).

If the importer is to submit the MDRs, the foreign manufacturer still bears responsibility for ensuring that the importer submits the MDR reports in compliance with all applicable MDR requirements. We would consider such a failure to report to be sufficient grounds to revoke the manufacturer's exemption from reporting.

3. WRITTEN PROCEDURES, RECORDKEEPING, AND PUBLIC DISCLOSURE

3.1 What are my requirements for developing, maintaining, and implementing written MDR procedures?

You are required to develop, maintain and implement written MDR procedures [21 CFR 803.17]. Your procedures must include internal systems that provide for the following [21 CFR 803.17(a)]:

- Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, including device-related complaints;[12]
- A standardized review process or procedure (based on the MDR regulation) for determining whether or not an event is an MDR reportable event; and
- Timely transmission of complete reports to us.

Your procedures must also include documentation and recordkeeping requirements for [21 CFR 803.17(b)]:

- Information that was evaluated to determine if an event was reportable;
- All medical device reports and information submitted to us;
- Any information that was evaluated for the purpose of preparing the submission of annual reports; and
- Systems that ensure access to information that facilitate timely follow-up and inspection by us.

Your written MDR procedures should establish policy and procedures that cover all the requirements of the MDR regulation. We recommend that you keep them as a separate document. If you combine them with other procedures (e.g., complaint handling or vigilance reports), the MDR portion should be in a separate section. Your procedures must describe how you will conduct your investigations of events that may be reportable [21 CFR 803.17(a)(2)]. For example, you may need to make multiple attempts to contact the reporter either by phone, fax, or letter to obtain information about the event before the investigation is closed. We expect you to make a "good faith effort" to obtain additional

[12] The QS regulation requires that complaints be investigated by a formally designated unit [21 CFR 820.198]. Manufacturers must evaluate events that may be subject to MDR requirements in accordance with the complaint file requirements in 21 CFR 820.198 [21 CFR 803.18(e)].

information including, when needed, a written request for information (see section 2.23 of this guidance for more information on what we believe constitutes a "good faith effort").

3.2 What are my requirements for establishing and maintaining MDR files and records?

You are required to establish and maintain complete MDR files in either written or electronic form and should identify them prominently as "MDR Files" so they can be located easily [21 CFR 803.18]. Your MDR files can be maintained as part of your complaint files required under the QS regulation. We will not consider an MDR report that you submit to be in compliance with the MDR regulation unless you evaluate the event or complaint in accordance with 21 CFR 820.198 of the QS regulation regarding investigation of device complaints [21 CFR 803.18(e)]. There must be a record of this investigation documented in the complaint file [21 CFR 803.18(e)].

Your files should include a record of each attempt to obtain information, and the nature of the response by the reporter. If MDR information cannot be obtained, you must document an explanation of why you could not obtain the required MDR information [21 CFR 803.17, 21 CFR 803.18, and 21 CFR 803.50(b)(3)]. This information should demonstrate that you made a reasonable attempt to follow up and obtain the relevant required information.

MDR files should be maintained for two years from the date of the event or a period equivalent to the expected life of the device, whichever is greater [see 21 CFR 803.18(c)], even if the event was determined to be not reportable or you have stopped manufacturing or distributing the device.

The "expected life of a device" is the time that a device is expected to remain functional after it is placed into use [21 CFR 803.3]. Certain implanted devices have specified "end of life" (EOL) dates. Other devices are not labeled with EOL dates, but are expected to remain operational through activities such as maintenance, repairs, or upgrades.

MDR files can incorporate references to other information sources, such as medical records, patient files, and engineering reports, and must contain [see 21 CFR 803.18 and 803.50(b)(3)]:

- Information in your possession or references to information related to the adverse event (e.g., test, laboratory and service records and reports, and records of investigations), including all documentation of the deliberation and decision-making processes used to decide whether the event was or was not reportable. You should also include the name, signature, and title of the person who made the decision. When applicable, the final assessment should indicate the cause of the event and what action, if any, you took to assure that the cause of the event was corrected or otherwise mitigated.

- Copies of all MDR forms, as required by 21 CFR part 803, including a copy of any Forms 3500A received from user facilities and importers, and other information related to the event that you submitted to us and other entities such as an importer or distributor. This information should include the original or a copy of the initial record and information related to the event. These records should include the available information needed to complete your report. The record may be a documented telephone call, a letter or fax, a service report, documents related to a lawsuit, a voluntary Form 3500 received from a health care professional or consumer, or a mandatory Form 3500A received from a user facility and/or importer.

Your events must be evaluated in accordance with the applicable requirements of 21 CFR part 820.

You must permit any of our authorized employees, at all reasonable times, to access, copy, and verify the records required by 21 CFR part 803, including MDR events [21 CFR 803.18(b)(2)].

3.3 What information contained in my MDR reports is subject to public disclosure and what information will not be disclosed?

Any report in our control, including a record of a telephone report, may be subject to public disclosure in response to a Freedom of Information Act request. However, before public disclosure of an MDR report, including any you have submitted to us and any FDA record of a telephone report, we will delete the following information [21 CFR 803.9(b)]:

- Information that constitutes trade secret or confidential commercial or financial information under 21 CFR 20.61;

- Personal, medical, and similar information (including the serial number of implanted devices), which would constitute a clearly unwarranted invasion of personal privacy under 21 CFR 20.63 (this includes the identity of the patient as well); and

- Names and other identifying information of a third party that voluntarily submits an MDR report. This includes physicians, health care professionals, or other hospital employees.

We will disclose to a patient requesting a report, all information in the report concerning that patient, except for any trade secret or confidential commercial or financial information [21 CFR 803.9(b)(2)].

When a user facility submits a report concerning one of your devices, as required by the MDR regulation, we will not disclose the identity of the facility except in connection with [21 CFR 803.9(c)]:

- An action brought to enforce section 301(q) of the FD&C Act, including the failure or refusal to furnish material or information required by section 519 of the Act;

- A communication to you concerning the report; or

- A disclosure to employees of the Department of Health and Human Services, the Department of Justice, or duly authorized committees and subcommittees of the Congress.

A publicly disclosable version of the medical device reports that we have received is available on the CDRH web page at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM, under the heading "Databases."

3.4 When I submit an MDR report, is the report considered an admission that my device caused or contributed to the reported event?

No, the submission of a report or related information to us and our release of that information is not necessarily an admission that you, your employees, or your device caused or contributed to the reportable event [21 CFR 803.16]. We have included such a disclaimer on Form 3500A at the bottom of the front page. You can also include your own disclaimer in MDR reports.

4. SPECIFIC ISSUES AND SITUATIONS

4.1 Delay in Surgery

4.1.1 For several years our firm has submitted an MDR for any situation in which a surgery is delayed. What is your position on this issue?

The event will be an MDR reportable event if your awareness of such an event reasonably suggests that your device may have caused or contributed to a death or serious injury or that your device has malfunctioned and the device or a similar device marketed by you would be likely to cause or contribute to a death or serious injury if the malfunction recurred. An event should not be considered to be an MDR reportable event solely on the basis of a delay in surgery. For example, a delay of surgery due to the surgical team setting up the wrong size device and requiring time to obtain the correct size device for the patient would not be a reportable event if the patient remains stable with no adverse consequences. However, firms should obtain details about the delay and the patient's condition to support the decision not to file an MDR report.

Each event must be evaluated to determine whether your device may have been a factor in a death or serious injury. If the failure of a device causes a delay in surgery and this delay may have caused or contributed to a death or serious injury to a patient, then this event would be reportable. If you determine that your device did not cause or contribute to a death or serious injury, the event may still be reportable if you determine that the device malfunctioned and the device, or similar device you market, would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

4.2 Expected Life of the Device

4.2.1 Can the expected life of a device be determined by the warranty?

No, the warranty period is not the same as expected life. The "expected life of a device" is the time that a device is expected to remain functional after it is placed into use [21 CFR 803.3]. You are not required by the MDR regulation to establish an expected life for a device.

4.2.2 For devices intended for periodic preventive maintenance, or some sort of a scheduled calibration time, is the expected life one calibration, one preventive maintenance cycle, or the overall life of the product?

We consider the "expected life of a device" to include the overall life of the product, not the time between calibrations or a preventive maintenance cycle (see section 3.2 of this guidance).

4.2.3 Does the expected life definition take into consideration routine maintenance recommendations that I make?

The expected life of a device may be established by assuming the device receives normal or recommended routine maintenance and service.

4.2.4 Am I required to report routine explants of implanted devices that have an expected life that is less than the life of the patient, such as tissue valves, vascular grafts, or routine revisions of orthopedic implants?

Certain implanted devices have a specified "end of life" date. If the implant has reached or is near the end of its established life expectancy, and is subsequently replaced without a device-related death or serious injury associated with the replacement, then it would not constitute a reportable event**,** even if surgery is involved. However, the event would be reportable if the device caused or contributed to or may have caused or contributed to a patient death or serious injury, or malfunctioned and the malfunction of the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if it were to recur.

4.3 Device Labeling

4.3.1 If my device labeling addresses the risks and complications associated with the use of a device, is an MDR required when a listed complication occurs?

Yes, the event would be reportable if the medical device caused or contributed to a death or serious injury, even if the complication was addressed in the device labeling. 21 CFR 803.3 defines "caused or contributed" to include a medical device that was or may have been a factor in a death or serious injury. Events that were anticipated or intrinsically caused by a device are not exempt from reporting.[13]

4.3.2 The labeling of my device states that another manufacturer's component is not compatible with my device and use of the two together would render my device inoperable. Would an adverse event resulting from this incompatibility be reportable under MDR?

The event would be reportable if a device-related death or serious injury may have occurred as a result of the incompatibility problem. However, because your labeling makes it clear that the devices should not be used together, the event would not be reportable as a device malfunction.

[13] See 60 Fed. Reg. at 63582-63583.

4.4 Diagnostic Devices

4.4.1 Is an event, indirectly caused by a failed diagnostic device, reportable?

Yes, we consider the failure of a diagnostic device to be reportable when it indirectly (or directly) causes or contributes to a death or serious injury, or would be likely to, if the failure were to recur.[14]

4.5 Difference of Medical Opinion

4.5.1 If there is a conflict of opinion about the role of my device in an adverse event, do I have to submit an MDR? For example, is an MDR required where a doctor performing a surgery does not believe my device malfunctioned, but another healthcare professional at the same facility says the device did malfunction?

If you become aware of information that one of your marketed devices may have malfunctioned, then you are required to investigate the situation and determine if the information you obtain reasonably suggests that the device did in fact malfunction and that the malfunction would be likely to cause or contribute to a death or serious injury if it were to recur [21 CFR 803.50]. Your investigation should include an evaluation of any differences in medical opinion. If, based on everything considered in your investigation, you determine that there was no device malfunction or that the device malfunctioned, but the malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur, then you would not have to submit a report [21 CFR 803.20(c)(2) and 803.22(b)(1)]. Otherwise, you would be required to submit an MDR report about the event.

4.6 Events Involving Same Patient on Different Days

4.6.1 How should I report adverse events involving the same patient and device that occur on different days?

If a patient experiences adverse events on different days with the same device, and the events are reportable, each occurrence should be reported as a separate submission.

4.7 Exemptions and Time Limits

4.7.1 How long is an exemption in effect once it is granted?

[14] See 60 Fed. Reg. at 63582.

Exemptions will not typically be time limited; however, we may revoke or modify in writing an exemption, variance, or alternative reporting requirements if we determine that protection of the public health justifies the modification or a return to the generally applicable reporting requirements [21 CFR 803.19(d)]. When a request is granted, any appropriate conditions will be specified, including any other reporting requirements to ensure the protection of public health.

4.8 FDA Access to Electronic Files/Data

4.8.1 Am I required to provide FDA access to my electronic files as well as my hard copy complaint and MDR files during an inspection?

Yes, if your official file is an electronic file or includes electronic files, then you must provide FDA full access because that is what you have chosen to use to meet your MDR recordkeeping requirements. MDR event files are written or electronic files which you are required to maintain [21 CFR 803.18(b)(1)-(2)]. For additional guidance about electronic records, see the guidance document: "Guidance for Industry, Part 11, Electronic Records; Electronic Signatures – Scope and Application" available at the following FDA web site: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072322.pdf.

4.9 Follow-up Investigations

4.9.1 How much effort must I make to get information about an event, or even to get the device back? Sometimes when I call a user facility no one wants to talk to me. How many times must I call or write before I can close the file?

MDR files must contain an explanation of why any information required by the MDR regulation was not submitted or could not be obtained [21 CFR 803.18(e)]. You must conduct an investigation and evaluate the cause of each event [21 CFR 803.50(b)(3)]. As stated in sections 2.23 and 3.1 of this guidance, there is no specified number of attempts a manufacturer must make to obtain information. However, you should demonstrate a "good faith effort." For example, calling a user facility during hours when you know someone is unable to respond would not be considered a "good faith effort." In addition, if you are unable to obtain the information through phone calls, we would reasonably expect you to try to contact the user facility in writing and specify a response date for the information you are requesting. In regard to getting the actual device for analysis, although we cannot mandate that a user facility return a device to you for analysis, we strongly encourage them to do so.[15] The fact that you do not get the device back, however, does not mean you do not have to analyze the event. We do not believe it is

[15] See 60 Fed. Reg. at 63589.

reasonable to close the files simply because the device was not returned. You should undertake activities such as review of other similar events, device history review, review of appropriate manufacturing processes, etc., where they will help you analyze the event (see also section 3.2 of this guidance).

4.10 Devices under Investigational Device Exemption (IDE)

4.10.1 I'm a US manufacturer of a device that has been cleared or approved for marketing in the US, and is also being studied under an approved IDE. What are the requirements for reporting an event involving the investigational use of the marketed device?

If a device is legally marketed in the US and is also under IDE, any adverse events that involve the investigational use of the marketed device are subject to reporting under both the IDE regulation and the MDR regulation. An individual who manufactures devices intended for use in humans solely for this person's use in research, that are not for sale, and who may be subject to alternative reporting requirements under the IDE regulations is exempt from MDR reporting requirements [21 CFR 803.19(a)(2)]. However, there is no exception to MDR reportable events under 21 CFR part 803 for devices that are marketed lawfully in the US and that are also used under an IDE. Further, there is no exception to unanticipated adverse device effect reporting under 21 CFR part 812 for "unanticipated adverse device effects"[16] associated with marketed devices that may be used as a control. Thus, certain events may be reportable under both IDE and MDR regulations.

4.11 Foreign Events

4.11.1 Does the MDR regulation apply to devices that are legally exported by US manufacturers to foreign locations if the device is not cleared or approved for marketing in the US?

If you manufacture a device that is exported under section 801(e) or 802 of the FD&C Act, you are subject to the MDR regulation as a manufacturer [21 CFR 803.1]. Failure to submit required reports is a prohibited act [section 301(q) of the FD&C Act, 21 U.S.C. 331(q)]. Therefore, manufacturers exporting devices under section 801(e) or 802 of the FD&C Act are required to comply with 21 CFR part 803, including the requirements for written MDR procedures [21 CFR 803.17], MDR files or records [21 CFR 803.18], and MDR reporting requirements [21 CFR 803.10(c)]. However, FDA generally does not intend to enforce the MDR reporting requirements for those devices exported under section 801(e) or 802 of the FD&C Act, except under certain circumstances. The circumstances under which FDA generally intends to enforce the MDR reporting requirements for such devices includes situations where there has been a device concern

[16] *See* 21 CFR 812.3(s) for definition of "unanticipated adverse device effect."

identified that necessitates that FDA have information about exported device adverse events. When such a device issue is identified, FDA expects to notify the affected manufacturer(s) regarding the submission of MDR reports for their exported devices.

4.11.2 I'm a US manufacturer of a device that has not been cleared or approved for marketing in the US, although the device is being studied in the US under an approved IDE. Is an event involving my device that occurred outside the US reportable under MDR in this situation?

If you manufacture a device domestically that is exported under section 801(e) or 802 of the FD&C Act, you are considered a manufacturer and are thus subject to the MDR regulation [21 CFR 803.1]. Failure to submit required reports is a prohibited act [section 301(q) of the FD&C Act, 21 U.S.C. 331(q)]. Therefore, manufacturers exporting devices under section 801(e) or 802 of the FD&C Act are required to comply with 21 CFR part 803, including the requirements for written MDR procedures [21 CFR 803.17], MDR files or records [21 CFR 803.18], and MDR reporting requirements [21 CFR 803.10(c)]. However, FDA generally does not intend to enforce the MDR reporting requirements for those devices exported under section 801(e) or 802 of the FD&C Act, except under certain circumstances. The circumstances under which FDA generally intends to enforce the MDR reporting requirements for such devices includes situations where there has been a device concern identified that necessitates that FDA have information about exported device adverse events. When such a device issue is identified, FDA expects to notify the affected manufacturer(s) regarding the submission of MDR reports for their exported devices.

The adverse event that occurs outside the US should be reported to the IDE program in accordance with 21 CFR part 812.

4.11.3 I'm a foreign manufacturer of a device that has been cleared or approved in the US and is also lawfully marketed in a foreign country. If an adverse event occurs in a foreign country with the device, must the event in the foreign country be reported under the MDR regulation?

Yes, FDA considers an event that occurs in a foreign country reportable under the MDR regulation if it involves a device that has been cleared or approved in the US – or a device similar to a device marketed by the manufacturer that has been cleared or approved in the US – and is also lawfully marketed in a foreign country. Devices may be manufactured to slightly modified specifications to meet standards in different countries. If these changes do not substantially alter the performance of the device, then any adverse events that are MDR reportable events relating to such modified devices should be reported under the MDR regulation (see section 2.14 of this guidance).

4.11.4 I'm a foreign manufacturer of a device that has not been cleared or approved for marketing in the US, although the device is being

studied in the US under an approved IDE. Is an event involving my device that occurred outside the US reportable under MDR in this situation?

No, you would not be required to submit MDR reports for events occurring in other countries for a device that is manufactured in a foreign country and that is not cleared or approved for marketing in the US. However, if you become aware of information that reasonably suggests a device has malfunctioned and that a similar device that you market in the US would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, then you should report the device malfunction that occurred outside the US.

An adverse event that occurs outside the US should be reported to the IDE program in accordance with 21 CFR part 812.

4.12 Manufacturer Ceased Marketing a Device

4.12.1 If I previously marketed a device that is still in commercial distribution, but have ceased manufacturing the device, do I still have an obligation to submit MDR reportable events?

Yes, as long as you remain in business, you have an obligation to report events involving any device that you manufactured, even if you cease marketing the device. Note that you are not responsible for MDR reporting if you transfer ownership of a PMA or 510(k) for one of your devices to another company, and the new owner explicitly agrees to be responsible for MDR reporting obligations. Both firms should maintain documentation of this arrangement for MDR reporting.

4.12.2 Firm A manufactured and distributed a device that was cleared for marketing under its 510(k), but later sold the 510(k) to another firm (Firm B). Who should submit the MDR reports for adverse events that involve the devices that Firm A manufactured?

Although Firm B is responsible for reporting adverse events for the devices it manufactures after it purchases the 510(k), Firm A remains obligated to report adverse events for the devices it manufactured. The packaging and labeling for the devices Firm A manufactured would identify Firm A as the manufacturer with corresponding address and contact information. If Firm B agrees to assume responsibility for reporting MDRs for the devices manufactured by Firm A, this arrangement should be documented with a written agreement between the two firms. Firm A should also request an exemption from FDA to end its MDR reporting obligation for the devices it manufactured. (See 2.27 of this guidance for information on requesting an exemption.)

4.13 Medical Intervention

4.13.1 If a health care provider notices that a medical device is malfunctioning (i.e., not performing as intended) and intervenes before the malfunctioning device can harm the patient (i.e., can cause or contribute to a serious injury or death), is this reportable?

The event would be reportable as a malfunction if the malfunction would be likely to cause or contribute to a death or serious injury if it were to recur. If the device malfunctions but an alarm alerts the user to intervene before there is any harm to the patient, the event should be reported as a malfunction because of the potential to cause or contribute to a death or serious injury if the malfunction recurred and either the alarm did not work or there was no one to respond. Your investigation of the event should also confirm and document that in this instance, the device malfunction did not cause or contribute to any change in the patient's condition that would be considered a reportable serious injury (see section 2.13 of this guidance for the definition of "serious injury").

4.14 Patient Information

4.14.1 It is very difficult to obtain patient information due to patient confidentiality in the health care setting. Is this information always necessary?

It is necessary to attempt to obtain the patient information required by 21 CFR 803.52, including patient identification, especially if the event involved a death or serious injury. However, we request that the patient be identified only by code, not by actual patient name.[17] This will protect the privacy of the patient. Other required information about the patient (e.g., age, gender, and weight) generally can be provided without affecting patient confidentiality.

4.15 Radiation Therapy

4.15.1 Exactly what constitutes an MDR reportable event involving my radiation therapy device where there was incorrect treatment but no demonstrable patient injury?

A radiation therapy device is capable of causing or contributing to a radiation-related death or serious injury. An event in which a person receives a radiation injury, such as a radiation burn, would be reportable if the device may have caused or contributed to a death or serious injury or it has failed to perform as intended (malfunctioned) and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

[17] See Instructions for FDA Form 3500A – Section A: Patient Information, A1: Patient identifier.

At this time, we have not adopted a radiation exposure or dose threshold for such injuries. A malfunction or problem related to a radiation treatment or planning system would have to be evaluated to determine if the expected outcome of the device failure or problem would be likely to cause or contribute to a death or serious injury to the patient if it were to recur.

4.16 Reports Based On Literature

4.16.1 Must I investigate and submit reports on MDR reportable events reported in literature sources?

Yes, if the information in the literature source is made known to you or to any of your employees, and the information reasonably suggests that a reportable event or events may have occurred, then you must comply with the requirements of the MDR regulation and make a reasonable attempt to investigate each event [21 CFR 803.3 – "Become aware" and 21 CFR 803.18(e)].

4.16.2 What guidance can you provide concerning how to report events found in scientific articles and other literature?

You must investigate each event reported in the literature source to determine if the information represents an MDR reportable event [21 CFR 803.18(e)]. If the information in the literature source and/or your investigation of the cited events reveals specific information about all or some of the reportable events, then you will need to report these events as individual reports. For example, you could contact the author of the literature source and request information about all or some of the patient and/or device-related events.

You should also try to determine if the events in the literature source match events otherwise made known to your firm, and whether the events may have been previously reported to us. If they do, then you do not have to submit a second initial report, but you do need to consider whether or not you are in receipt of additional information that should be submitted as a supplement [21 CFR 803.56] (see section 2.22 of this guidance).

We do realize that information from literature sources may not provide specifics about some or all of the events discussed and you may be able to provide us with only very limited information about each reportable event. For this reason, we would consider accepting one report for multiple reportable events where the source of the information is a literature document and, after investigation, you cannot obtain enough information about each identified patient and/or device mentioned, in order to provide a complete report for each reportable event.

Our instructions for completing Form 3500A address submission of a report for reportable events where the source of the information is a literature review (see instructions for Block G-3). In addition, we recommend the following for all reportable

events identified in literature sources (published or unpublished) when there is limited information about the device and/or the patient and follow up is not possible:

- Submit an individual report for each event type if more than one is identified. For example, if the literature source includes information about patient deaths, serious injuries and reportable malfunction events, you should submit three individual reports (one for each of these three event types).

- Submit an individual report for each device identified if the generic names of the devices are different. For example, if a literature source identifies your suspect devices as catheters and pacemakers, then you should submit two reports to cover these two different devices. You would also need to account for different event types (death, serious injury, or malfunction), as noted in the bullet above.

You should provide the following information in your submission:

- The most representative data available. For example, you should report the average patient age and weight, as well as the gender of the majority of patients involved. The date of the event should be reported as the date of the literature source, and the date of the report should be reported as the date that the literature first came to the attention of you or one of your employees.

- All the events covered by the report can be summarized in an EXCEL spreadsheet and attached to your report. You should include the following information in your summary:

    - Device identification information (brand name, model, or catalog number);

    - Patient and device problem codes; and

    - Manufacturer device evaluation and conclusion codes.

You should either attach a copy of the literature source to your report or provide the web address location for the article.

5. QUESTIONS CONCERNING COMPLETION OF THE MDR REPORT

NOTE: The form, instructions, and coding manual for completing the form can be obtained at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions/default.htm. The information in this chapter is intended to clarify certain issues and answer questions about completion of the form. It is not intended to change or modify, in any way, the form or instructions for completing Form 3500A.

Note: Information for electronic reporting can be obtained at eMDR – Electronic Medical Device Reporting.

5.1 General Questions

5.1.1 When submitting my initial report why can't I just fill in the parts of the form for which I have the information requested, and leave the rest of the form blank?

If the fields are left blank, we cannot determine what information was unknown to you or what information was simply overlooked. By completing each requested data element, you assure us that all elements were considered and reviewed. Please see the instructions for completing reports on paper at CDRH's web page http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149238.htm, or the information for electronic reporting at eMDR - Electronic Medical Device Reporting.

5.1.2 What are the most common problems you see in the way manufacturers fill out Form 3500A?

The most common problems that we encounter are as follows:

1. Duplicate report sequence numbers provided in the Manufacturer Report Number box and Block G-9.

   Each report must have its own sequence number to avoid confusion. [See 21 CFR 803.3 for the definition of "manufacturer report number."] You should not use the same sequence number on more than one report in any given year.

2. Multiple devices or events are included in the same report.

   If more than one of your devices is involved in a single MDR reportable event, and it is not apparent which device may have caused or contributed to the event,

then you must submit a separate report for each of your devices involved in the event [see http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149238.htm, "Manufacturers must complete and submit a separate Form FDA 3500A for each different suspect device"].

If a series of MDR reportable events occurs, then you must submit a separate report for each event. In addition, if the series of events involves more than one of your devices, and it is not apparent which device may have caused or contributed to the event or which device malfunctioned, you must submit a separate report for each of your devices involved in each event.

3. The Blocks in B-2 (Outcomes Attributed to Adverse Event) and B-5 (Description of Event or Problem) do not match or do not accurately represent the text contained in H-1 (Type of Reportable Event), H-10 (Additional Manufacturer Narrative), or H-11 (Corrected Data).

   If any information in Block B conflicts with the information in Block H, then you should provide an explanation in Block H-11 to address the conflict. For example, if a reporter marks "Death" in Block B-2 as the outcome, and after your investigation you determined that the patient did not die, you would provide this explanation in Block H-11.

4. Block D (Suspect Medical Device) is left blank or specific items within Block D are left blank.

   You should provide as much information as possible in this Block in order for us to properly identify the device and evaluate the event. It is important that you make a good faith effort to obtain the information.

5. An importer submits a report on behalf of the manufacturer without requesting an exemption.

   In order for an importer to be permitted to submit MDR reports that satisfy both the manufacturer and importer reporting requirements, the foreign manufacturer must first submit a request to us for an exemption from filing under 21 CFR 803.19. However, we recommend that the importer and the foreign manufacturer submit a joint request to us for an exemption from filing, specifying that the importer will submit the reports. The reporting firm must then complete Blocks A, B, D, E, F, G and H on the Form 3500A. See the discussion in section 2.32 of this guidance for more information on exemptions.

6. The contact name and telephone number are not provided in Blocks G-1 and G-2, respectively**.**

This information is important if we need to follow up on your report, either in writing or by telephone.

7. A 5-day report is submitted for an event that does not meet the 5-day report criteria.

   As explained in section 2.20 of this guidance, 5-day reports are required for an event that either: (a) necessitates remedial action to prevent an unreasonable risk of substantial harm to public health, or (b) for which we have requested the submission of 5-day reports [21 CFR 803.53].

   If the event necessitated remedial action and a 5-day report is required, you should also make sure to provide information required in Blocks H-7 and H-9.

8. A report is marked as a "follow-up" report, but no follow-up sequence number is provided.

   The sequence number must be provided as 1, 2, 3, etc., beginning with the first follow-up report submitted (e.g., first follow-up report = follow-up #1, second follow-up report = follow-up #2, and so on) [see Instructions for Completing Form FDA 3500A, G7].

9. No box is marked, or more than one box is marked, in Block H-1 (Type of Reportable Event).

   A reportable event should not be reported as multiple types of events and only one of these boxes should be marked. If the device malfunctioned, and the malfunction may have caused or contributed to a death or serious injury, mark either the box labeled "Death" or the box labeled "Serious Injury" as appropriate, but do not also mark the "Malfunction" box.

   If a single event caused or contributed to the death of one person and the serious injury of another, you should submit a separate report for each outcome. Furthermore, the box marked "Other" should not be used because, at this time, there are no "Other" types of events that are required to be reported by the MDR regulation. Events that do not involve an "MDR reportable event" should not be reported on Form 3500A.

10. Codes required to be entered in Block H-6 (Evaluation Codes) are put in boxes on the wrong row. For example, an evaluation method code might be entered in the space for evaluation results codes or evaluation conclusion codes.

    Make sure your codes are applicable and are placed in the proper space.

11. Block H-7 information (If Remedial Action Initiated, Check Type) is not provided when the event relates to a remedial action.

As discussed under common problem number 7, if you are submitting a 5-day report because of a remedial action taken, you must check the appropriate box in Block H-7 and enter information in H-9.

If you are submitting a 5-day report because we have requested that you do so, you should indicate in Block H-10 that we have requested the submission of a 5-day report for the event you are reporting. If the event is not associated with a remedial action, then you should not enter information in Block H-7 or H-9.

If your report is not a 5-day report and it is your initial report of the event, you should mark the "Initial" box to identify a 30-day report in Block G-7. Any associated remedial action should be identified in Blocks H-7 and H-9.

12. Event problem codes (patient problem codes and/or device problem codes) are not provided in Block F-10.

    These codes are important in helping us understand the adverse event and determining whether it presents a public health issue that needs to be addressed. When user facilities or importers fail to provide these codes to you, or they fail to provide correct or complete codes, you are required to provide the missing, incomplete, or corrected codes in Block H10/11 [21 CFR 803.52(f)(11)]. Often codes are not provided or, when they are provided, patient codes will be recorded as device codes and vice versa. You should make an effort to provide applicable or corrected codes and to label them properly. As indicated in section 2.8 of this guidance, a coding manual containing instructions on the use of patient and device codes is available on the CDRH web page at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm106737.htm.

    On July 1, 2009, CDRH made available a revised set of patient and device codes to use when reporting MDR mandatory adverse event reports. As of April 2, 2010, only these new codes may be used. Information on the new codes and their use is available on the CDRH web page at MDR codes.

5.2 Block A - Patient Information

5.2.1 How do I complete the field for patient name (Block A-1) when the patient is also the initial reporter (Block E)?

You should not record the patient's name in Block A-1. You should instead use a patient identifier in Block A-1 that will be applicable only for that patient. Any code that will prevent identification of the patient by the patient's name can be used. When the initial reporter is also the patient, you should provide the initial reporter's information in Block E-1. However, you should not indicate that the reporter is also the patient. You should

not leave the field blank, or it will appear that you forgot to supply the data, and you may get a letter from us requesting the missing data.

5.3 Block B - Adverse Event or Product Problem

5.3.1 What date is meant by "Date of this Report," in Block B-4?

The "Date of this Report" in Block B-4 is intended to be the date the initial reporter provided the information to the manufacturer, importer or user facility. [21 CFR 803.52(b)(4)]. In most cases, this date will be the date you became aware of the event.

5.3.2 How much detail do I need to use to describe the event?

Block B-5 provides an open space for your description of the event or problem. You are encouraged to provide all information known about the event, including: (i) how the device was involved; (ii) the nature of the problem; (iii) the required patient treatment; (iv) the patient outcome or final condition; and (v) any environmental conditions that may have influenced the event.

5.4 Block F - For Use By User Facility/Importer

5.4.1 If I complete Form 3500A for a user facility or importer event, do I include the information required by Block F in Block H-11, or should I complete Block F?

When you receive information from the user facility or importer (not on a Form 3500A) and you must complete Form 3500A, you must provide the information required by Blocks A, B, D and E in addition to Blocks G and H. Although you are not mandated to complete Block F, you should enter the patient and device codes that are required by Block F-10 in Block H-10/11.

If you are submitting your report electronically please refer to the electronic Medical Device Reporting (eMDR) - Home Page.

When the Form 3500A is received from the user facility or importer, we prefer that you prepare a separate Form 3500A with Blocks G and H completed and submit both forms. However, you may, at your discretion, add this information to the Form 3500A you received from the user facility or importer, if the information you received is complete and correct [21 CFR 803.20(a)(2)]. In this case, you should attach a copy of the 3500A from the user facility or importer to document the information that was received.

5.4.2 Does the omission of the data elements on a user facility or importer malfunction report relieve me from follow up and reporting information requested on the 3500A?

No, it does not. The MDR regulation requires, and the instructions for completing the Form 3500A clarify, that the manufacturer is required to provide any information missing on the user facility or importer report [21 CFR 803.50(b)(2)] (see also section 5.4.1 of this guidance).

5.5 Block H - Device Manufacturers Only

5.5.1 What is meant by "Evaluation codes" requested in Block H-6?

"Evaluation codes" are the manufacturer's perspective of the reported event. They are found in the coding manual (see the CDRH web page at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm106737.htm).

More specifically, the evaluation codes provide information about the:

(1) Method used to evaluate the medical device involved in the reported event (method of evaluation codes);

(2) Results of the evaluation (evaluation results codes); and

(3) Conclusions made concerning the relationship of the device to the reported event (evaluation conclusion codes).

The codes for method of evaluation are broken into two groups: (1) the source of the device evaluated, and (2) the type of evaluation performed.

The source of the device evaluated codes allow for the possibility that a device other than the specific device involved in the event could be evaluated, such as a device from the same lot, or a reserve sample.

Codes for the result of the evaluation are divided into three basic categories and two specific categories. The basic categories are problems related to the:

(1) Device,

(2) Use of the device, and

(3) Physiological/procedural factors.

The two specific categories are problems related to:

(1) Device components/subassembly failures, and

(2) Computers, imaging systems and microprocessors.

At least one code from one of the basic categories should be chosen if an evaluation was made. Additional codes from any or all of the basic categories may be entered, as appropriate. One or more codes from any of the specific categories may also be chosen, as appropriate.

5.5.2 The instructions for completing Form 3500A state that conclusion codes should be entered even if the device is unable to be evaluated. How is this possible? If the actual device cannot be evaluated, shouldn't Block H-6 be left blank?

You do not need to have access to the device in order to be able to draw a conclusion concerning the event. The conclusion codes provide for situations where the device may not be available for evaluation. In this case, you may select one or more of the applicable codes. In addition, conclusion codes may be drawn based upon evaluation of retention samples, or other information in your possession.

You must provide at least one evaluation conclusion code, even if the code for "no conclusion can be drawn" is the only code you can use. It is possible to have more than one evaluation conclusion code, but the field should not be left blank.

5.5.3 Because Block H-6 has 4 boxes for method, results and conclusions, do I put one number in each box or the entire code in one box? If I put the entire code in one box, am I then limited to just four codes for each category?

Each box should contain all the appropriate numbers for a complete code (you should not put only one number per box). Although the form has just four boxes per category, you may use more codes by entering the additional codes in Block H10/11 or by attaching an addendum page to your report that provides the additional codes. For each additional evaluation code provided, please indicate whether it is a method, results, or conclusion code.

5.5.4 Should I check a box under H-7 to identify a correction I make to the device involved in the MDR report? When should I provide information under H-7? What should I report under H-9?

If your investigation of a device malfunction leads you to make a correction only to that one device, your correction would not be considered a remedial action that should be reported under H-7. Block H-7 should be used only to report a situation in which your firm takes action (other than routine maintenance or servicing of a device) to more than one device to prevent the recurrence of a reportable event.

Block H-9 should be used to provide FDA with the number of the report filed with the FDA in accordance with the Correction and Removal regulation, 21 CFR part 806. As

required by section 519(g) of the FD&C Act and 21 CFR 806.10, a firm that initiates a device correction or removal to (1) reduce a risk to health posed by the device or (2) to remedy a violation of the FD&C Act caused by the device which may present a risk to health, is required to report this action to FDA within 10 working days of initiating such correction or removal. The Reports of Correction and Removal regulation, 21 CFR part 806, specifies the information that must be included in this report, as well as the format the firm should follow when assigning the correction/removal reporting number. This number consists of the registration number for the responsible firm, the date of the report using MM/DD/YY format, a 3 digit sequential number for each report made on that date (i.e., 001, 002, 003, etc.), and the report type designation (e.g,, "C" for a report of correction or "R" for a report of removal).

You may need to submit an MDR report before the decision is made to implement a corrective action. In that case, a supplemental MDR should be filed within 30 days of the decision to take a remedial action.

If your firm is not initiating a remedial action in response to the MDR report you are filing, you should leave H-7 and H-9 blank.

APPENDIX A

BASIC REQUIREMENTS FOR USER FACILITIES, IMPORTERS AND DISTRIBUTORS

A.1 Basic Requirements for User Facilities

A "device user facility" is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office [21 CFR 803.3]. A user facility does not include school nurse offices and employee health units. User facilities are required to submit MDR reportable events, within 10 work days after the day they become aware of a reportable event as follows:

- Reports of device-related deaths must be reported to us and to the device manufacturer, if known [21 CFR 803.10 and 21 CFR 803.30]; and

- Reports of device- related serious injuries must be reported to the manufacturer (or to us when the manufacturer is not known) [21 CFR 803.10 and 21 CFR 803.30].

User facilities are also required to:

(1) Submit to us, on an annual basis, a summary of all death and serious injury reports submitted during the reporting year [21 CFR 803.10(a)(2) and 21 CFR 803.33];

(2) Develop, maintain and implement written MDR procedures [21 CFR 803.17]; and

(3) Maintain files related to medical device adverse events [21 CFR 803.18].

A.2 Basic Requirements for Importers

An "importer" is any person who imports a device into the US and who furthers the marketing of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user of the device. It should be noted, however, that a person who repackages or otherwise changes the container, wrapper, or labeling of the device or device package is considered to be a manufacturer of the device [21 CFR 803.3].

Importers are required to submit MDR reportable events, within 30 calendar days after the day they become aware of a reportable event, as follows:

- Reports of device-related deaths and serious injuries must be reported to us and to the manufacturer [21 CFR 803.10 and 21 CFR 803.40]; and

- Reports of device-related malfunctions must be reported only to the manufacturer [21 CFR 803.10 and 21 CFR 803.40].

Importers are also required to:

(1) Develop, maintain and implement written MDR procedures [21 CFR 803.17]; and

(2) Maintain files related to medical device adverse events [21 CFR 803.18].

A.3 Basic Requirements for Distributors

A "distributor" is any person, other than the manufacturer or importer, who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user [21 CFR 803.3]. It should be noted, however, that, as is the case with importers, a person who repackages or otherwise changes the container, wrapper, or labeling of the device is considered to be a manufacturer of the device.

Distributors are only required to establish and maintain device complaint records (files) [21 CFR 803.18(d)].